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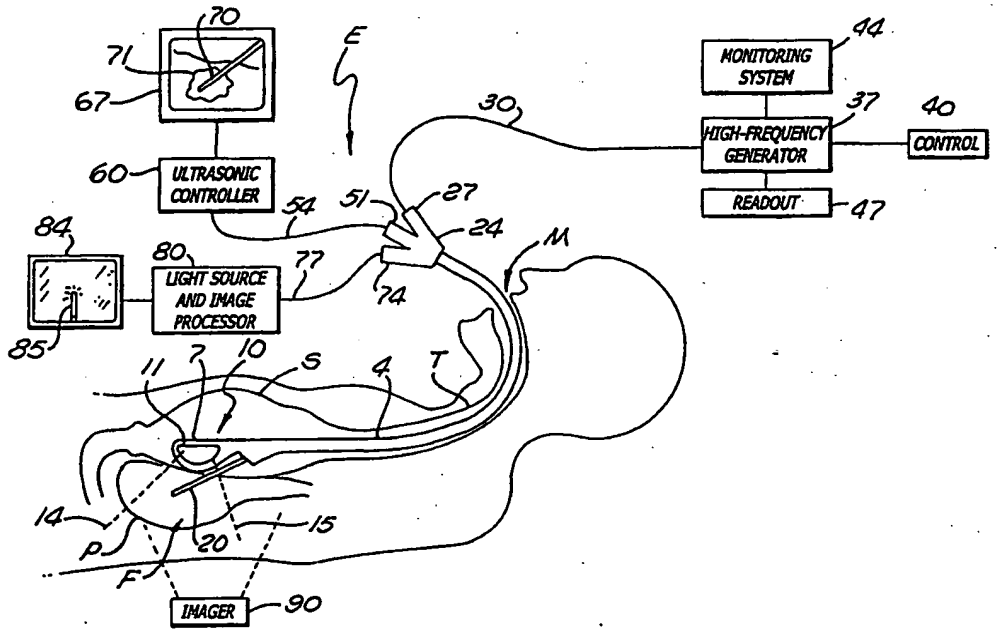

(57) Abstract

A trans–lumenal heat ablation system for the destruction of cancerous tumors includes an ablative element passed through an endoscope. In one embodiment, the ablative element is a radio–frequency electrode with a tissue–piercing point at its distal end so that when it emerges from the endoscope it can pierce the wall of the bodily lumen or passageway into which the endoscope has been placed. An ultrasonic imaging device within the endoscope provides image guidance of the tip of the electrode placed within the tumor volume.

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METHOD AND SYSTEM FOR TRANS-LUMENAL RADIO-FREQUENCY ABLATION THROUGH AN ENDOSCOPE

FIELD OF THE INVENTION

This invention relates generally to advances in medical systems and procedures for prolonging or improving human life. More particularly, this invention relates to an improved method and system for ablating clinical abnormalities such as tumors through the use of a high frequency electrode or a laser fiber that is passed within an endoscope in a bodily passageway and that trans-lumenally pierces the wall of the passageway.

BACKGROUND OF THE INVENTION

It is of increasing importance to treat diseases with minimally invasive techniques. For example, use of minimally invasive cannulae or endoscopes within the body reduces the trauma from surgery and enables access and visualization of internal structures without major surgical wounds. This is especially important in highly inaccessible areas such as in the gut, pancreas, abdomen, genitourinary tract, and so on. Access through a natural bodily opening or lumen such as the throat, rectum, urethra, or vessels saves further trauma.

There exist today advanced endoscopic systems, some with rigid and others with flexible, elongated shafts, to gain visual access and mechanical access through natural bodily lumens. Certain flexible endoscopes also have built-in ultrasonic scanning heads so that they can visualize tissue proximate to the distal end of the endoscope's tip by ultrasound scanning. By reference, see the gastroenterological endoscopes of the Panasonic and Olympus companies.

High energy or electrical current probes have been passed through an endoscope to coagulate structures on the surface of bodily lumens. For example, hemorrhaging surfaces of the stomach have been treated by inserting an endoscope into the stomach through the throat. An electrical coagulation probe is passed through the endoscope and put in contact with the tissue

that is bleeding. Electrical current can be passed through the electrode to thereby coagulate the bleeding tissue and to stop the hemorrhage.

Endoscopes together with radio-frequency electrodes have been used to treat benign prostatic hyperplasia, which is an enlargement of the prostate that causes urethral obstruction. One such procedure, called "trans-urethral needle ablation" or "TUNA," involves passing a radio-frequency (RF) instrument through a cystoscope (a rigid endoscopic device used for viewing in the urethra) into the urethra. The cystoscope is first placed in the urethra for visualization of the urethral wall in the region of the prostate. Once in place, a radio-frequency electrode is passed inside the cystoscope to the position of the open end of the cystoscope near the urethral wall. A tip of the radio-frequency electrode is pushed out along an off-axis path to pierce the urethral wall so that it passes into the prostatic tissue outside of the urethra. Radio-frequency energy from an external generator system is then applied to the radio-frequency electrode tip in the prostatic tissue to ablate the tissue outside the urethral wall. For further explanation of such a system and procedure, see the paper by Goldwasser, et al., entitled "Trans-Urethral Needle Ablation (TUNA) of the Prostate Using Low-Level Radio-Frequency Energy: An Animal Experiment Study;" *Eur. Urol.*, Vol. 24, pp. 400-405, (1993). Also, product literature on the TUNA system available from a company named Vitamed, Inc. Menlo Park, California, carries some description of the procedure.

The TUNA cystoscope is a rigid tube. It carries a straight fiber optic visualization channel so that the surgeon can view the scene directly ahead and slightly to the side of the opening at the distal end of the cystoscope. It is through that opening that the radio-frequency electrode passes and then pierces the urethral wall to enter the prostatic tissue. Although there is some degree of visualization intra-lumenally, that is, before the electrode pierces the urethral wall, there is no trans-lumenal visualization of the electrode tip in its placement after the piercing of the urethral wall. Thus, the TUNA procedure is a relatively blind procedure in the sense that the end of the RF electrode, once having penetrated the target tissue, cannot be seen. Furthermore, a straight, rigid endoscope, such as the urethral cystoscope, can not be used in many clinical settings. For example, to access the stomach, throat, or portions of the colon through the rectal opening, a straight endoscope is inadequate.

It would be desirable to be able to perform radio-frequency ablation procedures in many organs throughout the body. However, many of these organs, such as the pancreas, are very difficult to access with an RF electrode in a minimally invasive way. For instance, a tumor which is 2 centimeters deep within the pancreas cannot be seen with a conventional endoscope and therefore cannot be treated with a blind electrode approach. Percutaneous techniques involving passing electrodes through the skin are technically difficult, and associated visualization and navigation methods are elaborate and technically challenging. In other cases, such as with ailments of the gut or the abdomen, it may be desirable to ablate tissue and internal organs that lie adjacent to or several centimeters away from a natural bodily lumen.

Consequently, the techniques described above are limited in that they are not well-adapted to performing RF ablation in deep-lying tumors. Among the limitations of these techniques are the restrictions of using a straight endoscope and the lack of extra-lumenal imaging to control positioning of a radio-frequency electrode. Accordingly, an effective technique for performing minimally invasive, trans-lumenal radio-frequency ablation with image guidance through a natural bodily lumen is desirable for the purposes of treating cancerous tumors and other clinical diseases associated with bodily organs.

SUMMARY OF THE INVENTION

The present invention is directed to a system and procedure for trans-lumenal radio-frequency (RF) heat ablation of bodily tissue through and by the use of an RF electrode or a laser fiber that is passed through an endoscope. The system and procedure of the present invention are different than any of the systems and procedures discussed in the Background section above. The advantages of the present system and method reside, in part, in their superior ability to access non-superficial tumors and to provide image guidance. Image guidance mechanisms may be provided within the intra-lumenal endoscope itself or from an external image guidance apparatus to visualize the position of the RF electrode or laser fiber tip in the target tissue.

As one example, a tumor of the pancreas can be effectively treated using the present minimally invasive system and technique. The technique of the present invention involves inserting a flexible endoscope through the throat to reach the region of the stomach wall. One

portion of the stomach wall is in close proximity to the pancreas, which in this example contains a cancerous tumor identified by previous CT or MRI scanning. A long radio-frequency electrode is passed through the flexible endoscope. The electrode has a pointed tip which emerges through an opening in the distal end of the endoscope thereby enabling piercing of the stomach wall to penetrate the pancreas. An ultrasonic imaging head is built into the distal end of the flexible endoscope to visualize the pancreatic tissue near the distal end. The position of the tip of the radio-frequency electrode can then be adjusted under direct ultrasonic visual guidance, so that it can be placed into the pancreatic tumor. The RF electrode is then connected to an RF generator external to the body, thereby producing a heat ablation of the pancreatic tumor. According to clinical needs, other visualization methods such as MRI, CT, or external X-ray or external ultrasound could be used to assist visualization of the electrode tip as its emerges from the endoscope.

In contrast to the endoscope-directed intra-lumenal coagulation discussed in the Background section above, the RF electrode of the present invention has the advantage that it can be used to pierce the natural lumen wall; that is, it is used trans-lumenally. It thus enables treatment and ablation of tumors which lie deep within tissue in the region of a portion of a natural lumenal passage in the body.

The present invention procedure has the further advantage of being able to control the positioning of the RF electrode through intra-lumenal image guidance via ultrasound, or through external image guidance using ultrasound or other image modalities. This reduces the risks associated with blind procedures such as the TUNA procedure cited above.

Also, the present technique, system, and method has the advantage that it enables use of flexible endoscopes, not just the straight cystoscope employed in the TUNA procedure. This makes possible access to a much wider range of target sites and cancerous tumors. For example, tumors in the liver, kidney, spleen, and pancreas may be accessed through a flexible endotrachial endoscope. Such access may further be enhanced by endoscopic ultrasonography built into the endoscope itself.

In other examples of the present invention, other forms of endoscopes can be used to meet clinical needs in other part of the body. For example, a bronchoscope enables access to the lung

to perform RF ablation of tumors of the lung and mediastinum. A choledochoscope can be used to access the bile ducts for ablating tumors in the vicinity of the hepatic portal and biliary tree. Angioscopes can be used with RF electrodes according to the present system and invention to access organs through the vessels or arteries of the patient's body. Cranial endoscopes or flexible cranial endoscopes may access portions of the brain or endocranial cavity for this purpose. Ureteroscopes can be used for treating the upper genitourinary tract.

These features and advantages as well as others of the present method and system will become apparent in the detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings which constitute a part of the specification, embodiments exhibiting various forms and features hereof are set forth, specifically:

FIGURE 1 is a schematic diagram showing a portion of a patient along with a system according to the invention for performing trans-lumenal radio-frequency (RF) ablation of the pancreas using a flexible endoscope passed into the stomach through the throat;

FIGURE 2 illustrates a portion of an intra-lumenal ultrasonic imaging endoscope head with an optical viewing channel and a trans-lumenal radio-frequency electrode piercing a bodily lumen wall to penetrate a target volume outside the lumen; and

FIGURE 3 is a flowchart of the process employed in operating a system in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring initially to Figure 1, in a system in accordance with the present invention, a flexible endoscope E is inserted into the stomach S of a patient through the patient's mouth M and throat T. The endoscope E has a flexible, elongated body 4 that can be manipulated to direct a distal end 7 of the endoscope E into the stomach S. The operating field of the endoscope may include organs within, near, or around the stomach S in this illustration. Inside the distal end 7 of the endoscope E is an ultrasonic scanner 10 having a scanning head 11 capable of scanning a field of view F demarcated by dashed lines 14 and 15. This field of view F may include an organ such

as the patient's pancreas P, which lies near the stomach. Thus, in the illustrated embodiment, the ultrasonic scanner 10 is capable of scanning a portion of the wall of the stomach S and the nearby pancreas P.

To give a specific illustration in accordance with the system of Figures 1 and 2, an RF electrode 106 having a stainless steel shaft 111 approximately one to several millimeters in diameter is partially covered with an insulating coating (illustrated by hatched lines 114 in Figure 2). In one embodiment of the invention, the coating is one of many standard plastic insulative materials. The shaft 111 has a tip 121 that in various embodiments may be a sharpened cone, trocar, bevel, or other tissue-piercing structure. For example, in one embodiment, 18-gauge stainless steel tubing is used for the elongated shaft 111 of the electrode 106 in Figure 2. An exposed tip portion 117 of the electrode shaft 111 has a length between one millimeter and several millimeters or several centimeters, depending on clinical needs. The entire length of the RF electrode 106 may be several centimeters to as long as 200 or 300 centimeters or more, depending on which orifice and lumen the endoscope is designed for in the patient's body.

Other materials may be used for the RF electrode shaft 111 and exposed tip 117, including MRI-compatible materials with low magnetic susceptibility, such as high-cobalt nickel, copper, or Inconel. In one embodiment, the electrode shaft 111 is fabricated in a spiral configuration for greater flexibility, such as in a Seldinger wire. In another possible embodiment, the shaft 111 comprises a wire construction coated by a catheter-like sheath, or alternatively, a catheter with a ring or helical coil external surface as part of its tip end. Examples of various electrode configurations can be seen in the article by E. R. Cosman entitled, "Radio-Frequency Lesions," from Gildenberg and Tasker (eds.), *Textbook of Stereotactic and Functional Neurosurgery*, New York, NY: McGraw-Hill (1996), and also in the article, "Physical Aspects of Radio-Frequency Energy Applications," by E. R. Cosman and W. J. Rittman, from Huang SKS, (ed.), *Radio-Frequency Catheter Ablation of Cardiac Arrhythmias: Basic Concepts and Clinical Applications*, Armonk, NY: Futura Publishing Company Inc. (1994).

The endoscope E itself may take any of various possible forms. In one embodiment of the invention, the endoscope E is a flexible device used for upper gastrointestinal (GI) endoscopy. Such devices are typically up to 1 meter long, and have a snake-like, flexible or steerable body 4

(Figures 1 and 2). In an alternative embodiment, the endoscope E is a gastroenterological endoscope for lower endoscopy in the rectum or bowel. In another alternative embodiment, the endoscope is a cystoscope for urological applications; these are typically much shorter in length. In further embodiments, the endoscope may be a bronchoscope or a choledochoscope for applications in the lung, mediastinum, and upper thorax; or an endoscope which is capable of being inserted into a vessel in the vascular system, such as a vein or artery; or an endoscope which is capable of being inserted into the bile ducts, renal collecting system, and upper urinary tract. For known examples of such endoscopes, see the product lines of the Panasonic and Olympus companies.

In the example of Figures 1 and 2, the RF electrode 106 is inserted into a tumor 108 (the outline of which is indicated in a sectional view in Figure 2). Once the exposed tip 117 has been positioned in the tumor 108, as identified via the ultrasonic scanner 10, the electrode 106 is connected externally to a high-frequency generator 37 (Figure 1), and radio-frequency ablation can begin.

To give illustrative RF parameters that may be used in such a procedure, the frequency of the radio-frequency energy used for ablation can range from a few to many hundreds or even thousands of kilohertz. In a preferred embodiment of the invention, as with other known ablation systems and procedures, the high-frequency generator 37 is set to a frequency in the range of 500 kHz (see, e.g., some of the generators sold by Radionics, Inc., Burlington, Massachusetts). In one embodiment of the invention, the RF electrode 106 has at least one temperature sensor 118 (such as a thermocouple or a thermistor) attached to the exposed tip 117. The temperature of the tissue surrounding the exposed tip 117 can then be monitored during the heat ablation process via a monitoring system 44 used in association with the generator 37, as illustrated in Figure 1.

Typically, the power output from the generator 37 that is delivered to the tumor 108 through the RF electrode 106 is raised to an appropriate level to heat ablate the tumor. If temperature monitoring is performed, this can mean that the RF output is raised sufficiently to heat the tissue near the exposed tip 117 to greater than approximately 45°C. Depending on clinical needs, tissue temperatures as high as 90 to 100° C may be necessary. Multiple passes of the electrode into the tumor in different positions can further enlarge the heat ablation volume. In

one embodiment of the invention, a cooling system is employed to circulate coolant through the electrode to produce even larger-sized lesions without overheating the tissue near the exposed tip 117. By reference, see the paper entitled "Hepatic Metastases: Percutaneous Radio-Frequency Ablation with Cooled-Tip Electrodes," L. Solbiati, S. N. Goldberg, T. Ierace, et al., *Interventional Radiology*, 205:367-373, 1997.

Typically, lesions of up to several centimeters in diameter can be accomplished by using an approximately 18-gauge radio-frequency electrode tip 117 having a length of approximately 1 to 2 cm, raised to a temperature of around 90°C and kept at that temperature for 30 seconds to several minutes. As discussed above, the electrode 106 can range in diameter from 0.1 to several millimeters, and its length can range from 3" to 30" (approximately 8 to 80 cm) or more, depending on the kind and size of endoscope used and the clinical application.

The temperature, amount of power, and other system parameters (such as the length of the exposed tip 117) are related to the size of the lesion desired. Desired heat lesion sizes may vary from several millimeters to several centimeters, depending on clinical considerations. RF generators with RF power output ranging from several hundred watts may be needed, depending on the power requirements to ablate a particular tumor volume. Monitoring of lesion parameters during the heating process is typical, and in one embodiment of the invention, includes monitoring tip temperature and RF power, current, volume, impedance, and time.

As shown in the embodiment of Figure 1, an external imaging apparatus, shown as an imager 90, may be employed to guide or control the position of the RF electrode. In various alternative embodiments, a CT, MRI, X-ray, or ultrasonic scanner may be used to monitor the position of the distal end 7 of the endoscope E and the exposed RF electrode tip 117 in its placement within the target region. An MRI imager is capable of visualizing temperature isotherms, and ultrasound can identify cavitating boiling during such procedures. Thus, monitoring with these two modalities as well as other available imaging techniques can provide an indication of the size of the heat ablation volume which is being produced to treat the tumor volume.

Referring further to Figure 2, the flexible endoscope body 4 has a distal end 7 which includes within it an ultrasonic imaging head 11. The imaging head 11 has an ultrasonic

transmission and detection element 104 pointing toward one surface of the distal end 7. The detection element 104 is capable of imaging ultrasonic signals in an angular slice between the dashed lines 14 and 15 (as in Figure 1). This field of view of the ultrasonic scanner 10 preferably includes the tumor 108. The field of view also typically includes a portion of the lumenal wall 100, as well as the tissue near it between the dashed lines 14 and 15.

Information from the ultrasonic scanner head 11 is communicated by connection 54 to ultrasonic controller element 60 (Figure 1). Further in Figure 1, a graphics display 67 presents representations of the ultrasonic scanning image. For instance, in one embodiment of the invention, the graphics display 67 is a CRT display, on which a rendering 70 of a radio-frequency tip 20 within the tissue is shown together with a rendering 71 of the tumor 108 (Figure 2). A hub 24 of the endoscope has an adaption port 51 which accepts the connection 54 for the ultrasonic display.

As an alternative to the exemplary embodiments of Figures 1 and 2, the distal end 7 may include a portion of the components of an MRI scanner to produce MRI images of tissue near the distal end. This portion of components could comprise, for example, a sensing coil as the detection element 104 operating in cooperation with an external imaging apparatus 90 to produce MRI images through the controller 60 and the display 67.

Also shown in Figure 2 is an optical viewing element 130, which in a preferred embodiment is a fiber optic illumination and viewing channel. At its distal end is a viewing port 133, typically a lens. The optical viewing element 130 provides visual information on the passage of the exposed electrode tip 117 through the wall of the stomach S during its passage to the tumor 108. The hub 24 of the endoscope E (Figure 1) also has a port 74 through which the fiber optic channel 77, which transmits a visual image from the viewing element 130 to the outside world, is passed. A fiber optic light source and image processor 80 enables visual representations to be displayed on fiber optic display 84. In one embodiment of the invention, the fiber optic display 84 is a CRT display capable of showing a rendering 85 of the electrode 20. Thus, the display 84 may show a representation of the actual electrode 106 as it passes out through a port 124 at the distal end 7 of the endoscopic head, as shown in Figure 2.

As discussed above, the embodiment of Figure 1 includes a high-frequency generator 37.

In embodiments of the invention in which the electrode 20 is a radio-frequency electrode, the generator 37 is a radio-frequency generator providing an electrical output. In an alternative embodiment in which the endoscope E provides, for example, a fiber optic fiber or channel as an ablative element, then the generator 37 is a power source for the generation of laser signals and an accompanying power output.

A set of controls 40 for the high-frequency generator 37 (Figure 1) may comprise knobs, levers, or other control facilities enabled to control, for example, the power output from the generator 37. In one embodiment of the invention, the controls 40 allow the power output to be raised or lowered, started or stopped, or automatically or manually regulated. A readout 47 is also provided; in various embodiments it may comprise signal readouts or representations of the output parameters and other parameters associated with the generator 37. For example, in an embodiment of the invention in which the generator 37 is a radio-frequency generator, the associated parameters displayed on the readout 47 would preferably include indications of power, current, voltage, time, impedance, or other parameters associated with the radio-frequency output to the electrode 20. In the embodiment in which the generator 37 is associated with a fiber optic power source, then the readout 47 would preferably include indications of laser energy, frequency, and so on.

Also shown in Figure 2 is a satellite temperature monitor 150 with an associated readout and control system 154. In one embodiment, this apparatus includes a secondary temperature probe which can be inserted into, for example, the pancreas P, to monitor the temperature of tissue in the vicinity of the heat ablation region. For example, when a radio-frequency current is applied to the exposed electrode tip 117, then an ablative temperature zone may be indicated by a dashed line 110. In a preferred embodiment, the ablative temperature zone 110 is the isotherm corresponding to approximately 45°C. Any tissue within that isotherm may be permanently destroyed or ablated if the temperature is sustained for several seconds or minutes. The temperature monitor 150, which in one embodiment is a thermocouple temperature probe, is placed in the pancreas P (as an example) at a point adjacent to very critical structures such as nerves, vessels, or adjacent organs. The temperature sensor can be used to thereby ensure that the temperature of that region does not exceed a dangerous temperature during the course of heat

ablation of the target. The control and readout element 154 may be associated with the control and readout elements 40 and 47 (Figure 1), and in a preferred embodiment is integrated with them.

Referring now to Figure 3, a flow chart is shown to illustrate the process of extra-lumenal RF ablation by means of an intra-lumenal endoscopic system according to the invention. The procedure starts by inserting the desired endoscope into the appropriate body lumen (step 200). As discussed above, the endoscope may be either flexible or rigid, and is of a correct size and length to accommodate the clinical need. Depending on the application, the endoscope may be inserted into the appropriate body lumen such as the throat, bronchi, bile ducts, rectum, lung cavity, upper urinary or lower urinary system, vagina, heart, or arterial or venous vessels, etc. This positioning step 200 of the endoscope may include the use of external or internal imaging. For example, the endoscope may incorporate an internal ultrasonic head, as illustrated in Figures 1 and 2, and this can be used to achieve a desired position relative to the wall of the lumen in which it is inserted.

Once in the appropriate position, a high frequency electrode is passed through the endoscope channel (step 204). In one embodiment, the electrode has a tissue-piercing point; it punctures the lumenal wall for its trans-lumenal course into a target volume. This process is visualized (step 207) by way of an internal ultrasonic head within the endoscope, as illustrated above. External visualization using ultrasound, X-ray, MR, or CT may also be employed in addition to, or as an alternative to, intra-lumenal ultrasonic applications. These internal and/or external imaging methods may be continued during and after making the heat lesion to help in determining the adequacy of the ablation size and when to stop the heating process.

The positioning of the RF electrode tip to the desired target volume (step 211) is performed based on the intra-lumenal imaging apparatus or the external imaging apparatus. For example, the position of the exposed electrode tip 117 (Figure 2) can be adjusted based on the intra-lumenal scanning image on the display 67 (Figure 1) to achieve the appropriate positioning of the electrode tip within a tumor.

When the exposed RF electrode tip 117 (Figure 2) is in its proper position within the tumor, it is connected to the external generator 37, and high frequency power is delivered through

the electrode tip 117 to the tissue to ablate the tumor (step 214). This step can involve elevating the voltage, current, or power applied by the high frequency generator 37 to the electrode and therefore to the tumor tissue. The generator 37 may have manual controls such as knobs or levers, or other elements to control its output levels that can be actuated at this point. As an alternative, the process may be automated with an initial power setting or temperature level predetermined by the operator. The generator can then, under automatic or semi-automatic control, achieve the pre-selected parameter (such as temperature) and lock onto it by a feedback or control system within the generator 37. These elements are well-known in the art, and could be built into the control system 40 (Figure 1).

The step of adjusting and setting the output values (step 217) may include setting the RF power, voltage, or current levels, among other parameters. In one embodiment of the invention, this step includes achieving a desired temperature as recorded at the RF electrode tip 117 or at the satellite temperature monitor 150 placed elsewhere within the target volume or neighboring the operative field as illustrated in Figure 2. The time of RF power application may also be monitored. A pre-determined exposure time for high-frequency power to the electrode may also be desirable, depending on clinical needs, or may depend on the reading of temperature sensors in the RF ablation electrode at various positions. In one embodiment, multiple temperature sensors (e.g., 118) are placed along the RF electrode tip 117 to monitor the temperature at various positions within the target volume, and these temperatures can be read out on a temperature monitoring system 44 (Figure 1).

As an illustration, it may be known from clinical experience that a desired ablation volume can be achieved with a certain electrode geometry by applying a known value of RF power, current, or voltage, or alternatively by achieving a known temperature as recorded in one or more temperature monitors within the RF electrode or in surrounding tissue. These parameters may be monitored during the ablation process to influence the decision of the clinician to terminate or continue the process according to experience and parameter values. By reference, measurement of such parameters is illustrated by the RFG-3C lesion generator systems of Radionics, Inc. (Burlington, Massachusetts).

As discussed above, the duration and parameter settings used to achieve the desired RF

heat ablation volume or effect may, depending on the position and type of target to be ablated, determine the time at which the heating process is stopped (step 221). The decision to stop the procedure when it is believed that the tumor volume or other target structure of interest is adequately ablated is made at this time. As previously stated, the use of internal and/or external imaging or diagnostic detection methods may be involved in this step. For example, the use of ultrasonic scanning or MRI imaging may enable visualization of the heat ablation volume as it is being made or after it has been made. An ultrasound scan can identify gas bubble formation in the heated region and MRI can visualize thermal distributions, both of which may be an indication of actual lesion volume.

In accordance with one embodiment of the present invention, the clinician may choose an RF electrode tip geometry of a certain size, diameter, and length. He may know from experience that the insertion of an electrode trans-lumenally in a particular clinical site and delivering RF power to raise the tissue temperature near the electrode tip to a certain level will produce a known and adequate ablation volume. These criteria may be used by the clinician to induce sufficient ablation sizes. In accordance with another embodiment of the present invention, the RF electrode may not have a temperature sensor. The correlation of ablation size desired for a given electrode tip geometry may be determined by considering RF parameters such as power, output, voltage, and current. Generally, it may be known that RF power or current levels greater than certain values for a known electrode geometry will produce a desired size of ablation volume. In that case, the clinician may select the criteria of power and time to determine a desired ablation effect. Variations of the use of such parameters are embodied in the process set forth in Figure 3.

In accordance with another embodiment of the present invention, if CT, MR, X-ray, or ultrasound images are used to monitor the ablation size, then they may be used to decide an adequate ablation size. For example, certain MR images can represent thermal distribution around the electrode and thus indicate the ablation zone. This may be used as exemplary criteria in determining when to terminate the ablation process, as in step 221.

Using extra-lumenal RF electrodes in combination with endoscopes and endoscopic ultrasonography has the advantages of making accessible target volumes such as tumors in organs that are near body lumens and cavities. The present system and method thereby enable image-

guided control of radio-frequency ablation with minimal invasion. Tumors of the pancreas, liver, intestines, lungs, spleen, kidney, and upper and lower digestive system may be reached in this way, and accurate placement of ablation volumes can be made without the need for major surgery. Under image-guided control, such as endoscopic ultrasonography as described above, monitoring of the process and electrode placement becomes more accurate. These advantages will reduce the trauma to the patient, thereby permitting minimally invasive ablation to be administered to patients in frail health who cannot withstand open surgery, and reduce hospital expenses by minimizing hospital stay.

A further advantage of the present invention is that it enables precise control of the placement of electrodes in organs which otherwise may not be amenable to open surgery. For example, with ultrasound combined in the endoscope, visualization of the heat ablation of the tumor can be gauged in a visual and quantitative way. Because most bodily tissues remain intact, the visualization of the tumor by imaging remains largely undisturbed by the minimal invasion of the RF electrode. This is in contrast to open surgery, in which large position shifts can take place during surgical incision and retraction.

A further advantage of the present system and method over previous use of coagulation through endoscopes is that it is not limited to coagulation or burning of the lining of the lumenal structure. The present invention greatly expands the scope of, for example, radio-frequency ablative coagulation to much deeper structures within the organs near to the lumenal structure.

Yet a further advantage of the present system and method is that it minimizes risk to the membranes or the mucosal structures of the lumen through which the RF electrode is passed. In a preferred embodiment of the invention, the RF electrode or other delivery means is sufficiently small-gauged so that it will not cause hemorrhage or permanent damage to the lumenal surface. By ultrasonography, the placement of the exposed RF electrode tip, for example, can be deep enough and away from the lumenal lining to prevent destruction of the lumenal lining from the RF heat itself.

Because the minimally invasive nature of the present invention is better tolerated by patients who may be otherwise too weak to withstand surgery, a wider population of patients will be suitable for this method. The minimally invasive character of the treatment will also reduce

side effects such as bleeding, the need for heavy anesthetics, prolonged hospitalization and recuperation, and convalescent care. All of these advantages have the potential to reduce hospital and medical reimbursement expenses.

While various forms and embodiments of the trans-lumenal radio-frequency ablation system and method involving various electrode designs and various temperature sensors and monitoring systems have been described in detail above, it should be recognized that other forms may be used. A wide variation of parameters for the electrode size, shape, geometries, curvature, and materials may be used without departing from the scope of the invention. For example, an electrode may be pre-shaped in a curved configuration to permit aiming the electrode in a desired direction once it has projected beyond the opening of the endoscope. Different geometries of electrode may be suitable for different clinical needs or target sites, and these can be developed by those skilled in the art without departing from the scope of the invention. Electrode structures having multiple electrode tips to fan out into the tumor volume may also be used. In an alternative embodiment, bipolar electrodes can be used, in which one or more separate electrical conductive surface areas are present on or along the elongated electrode shaft. The different electrode areas can be raised to different high frequency voltages at the same or different times to alter or grade the shape of the heat ablation region. Furthermore, the high frequency electrode can be cooled internally or by ejection of a fluid out of the tip region. In one embodiment, cooled saline injected into the proximal hub 24 (Figure 1) runs through a channel inside the endoscope E and flows out of the distal end 7 near the electrical contact so as to cool the tissue near the tip 117 (Figure 2).

It is also important to note that various frequency ranges may be employed by the RF generator 37. For example, low radio-frequency signals in the range of 10 to 50 kHz, intermediate radio-frequency signals between 50 and 1,000 kHz (1 MHz), or high radio-frequency into the microwave range of tens or hundreds of megahertz may be used, all without departing from the scope of the invention. Moreover, other elements analogous to the electrode 20 in Figure 1 may be used within the flexible endoscope, using endoscopic ultrasonography to produce extra-lumenal ablation. For example, the radio-frequency electrode could be replaced by a laser fiber. This may transmit optical energy from a laser generator (replacing the high-frequency

generator 37 of Figure 1) through a carrier 30, which may include fiber optic bundles to deposit energy in the region of the tumor 108 (Figure 2). Thus in Figures 1, 2, and 3, the ablator or ablative element used with the flexible endoscope and in combination with image-guided ultra-sonography and other imaging means may be considered generally as one of several known ablation systems. The device may include, therefore, electrical current and power, or optical current and power, or microwave antennas to produce the heat ablation of the target volume.

In view of these considerations, as would be apparent by persons skilled in the art, implementations and systems should be considered broadly and with reference to the claims set forth below.

WHAT IS CLAIMED IS:

1. A system for trans-lumenal high frequency heat ablation of extra-lumenal tissue within a patient's body, comprising:

an energy generator;

a flexible endoscope for insertion into a lumen of the patient's body, wherein the endoscope comprises a distal endoscope tip; and

an ablator adapted to be received by the endoscope, wherein the ablator has a tissue-piercing distal ablator tip capable of emerging from the distal endoscope tip to pierce the wall of the lumen.

2. The system for trans-lumenal high frequency heat ablation of claim 1, wherein the ablator tip has a conductive surface acting as an electrode, and wherein the energy generator is capable of transmitting an electrical signal to the ablator tip to accomplish heat ablation.

3. The system for trans-lumenal high frequency heat ablation of claim 1, wherein the flexible endoscope comprises an ultrasonic imaging scanner within its distal tip, and wherein the scanner provides image data representative of the position of the ablator relative to a target within the patient's body.

4. The system for trans-lumenal high frequency heat ablation of claim 1, further comprising an imaging apparatus external to the body of the patient to provide image data representative of the position of the ablator relative to a target within the patient's body.

5. The system for trans-lumenal high frequency heat ablation of claim 4, wherein the imaging apparatus is a CT, MRI, X-ray, or ultrasonic imaging device.

6. The system for trans-lumenal high frequency heat ablation of claim 2, wherein the endoscope is adapted to be inserted down the patient's throat and into the patient's stomach,

allowing the distal endoscope tip to be positioned near a portion of the stomach wall so that the distal ablator tip can penetrate the stomach wall and be positioned near or in a tumor located in the patient's pancreas.

7. The system for trans-lumenal high frequency heat ablation of claim 6, wherein the endoscope comprises an ultrasonic imaging scanner disposed within said distal endoscope tip to visualize the portion of the distal ablator tip near or in the tumor in the pancreas.

8. The system for trans-lumenal high frequency heat ablation of claim 1, wherein the distal ablator tip comprises a temperature sensor to monitor the temperature of said tissue to be ablated.

9. A system for trans-lumenal high frequency heat ablation of extra-lumenal tissue within a patient's body, comprising:

an energy generator;

an endoscope for insertion into a lumen of the patient's body, wherein the endoscope comprises a distal endoscope tip comprising an ultrasonic imaging scanner, and wherein the scanner provides image data representative of the position of the ablator relative to a target within the patient's body; and

an ablator adapted to be received by the endoscope, wherein the ablator has a tissue-piercing distal ablator tip capable of emerging from the distal endoscope tip to pierce the wall of the lumen.

10. The system for trans-lumenal high frequency heat ablation of claim 9, wherein the ablator tip has a conductive surface acting as an electrode, and wherein the energy generator is capable of transmitting an electrical signal to the ablator tip to accomplish heat ablation.

11. The system for trans-lumenal high frequency heat ablation of claim 10, wherein the endoscope is adapted to be inserted down the patient's throat and into the patient's stomach,

allowing the distal endoscope tip to be positioned near a portion of the stomach wall so that the distal ablator tip can penetrate the stomach wall and be positioned near or in a tumor located in the patient's pancreas.

12. The system for trans-lumenal high frequency heat ablation of claim 10, wherein the distal ablator tip comprises a temperature sensor to monitor the temperature of said tissue to be ablated.

13. A method for performing heat ablation of a target volume in a patient's body, comprising the steps of:

inserting a flexible endoscope into a lumen of the body;

positioning a distal end of the endoscope at a point in the lumen near the target volume;

passing an ablator through the endoscope to the distal end of the endoscope;

penetrating a wall of the lumen with the ablator to reach the target volume; and

applying energy to the ablator to ablate the target volume.

14. The method of claim 13, wherein the positioning step employs an imaging system located at the distal end of the endoscope.

15. The method of claim 13, wherein the positioning step employs an imaging system external to the patient's body.

16. The method of claim 13, wherein the penetrating step employs an imaging system affixed to the distal end of the endoscope to identify the position of the ablator with respect to the target volume.

17. The method of claim 13, wherein the applying step comprises the steps of:

identifying a set of initial parameters for an energy generator; and

transmitting a signal representative of the initial parameters from the energy generator to the ablator.

18. The method of claim 17, wherein the applying step further comprises the steps of:

measuring at least one condition; and

controlling the energy generator based on the condition measured.

19. A method for performing heat ablation of a target volume in a patient's body, comprising the steps of:

inserting an endoscope into a lumen of the body;

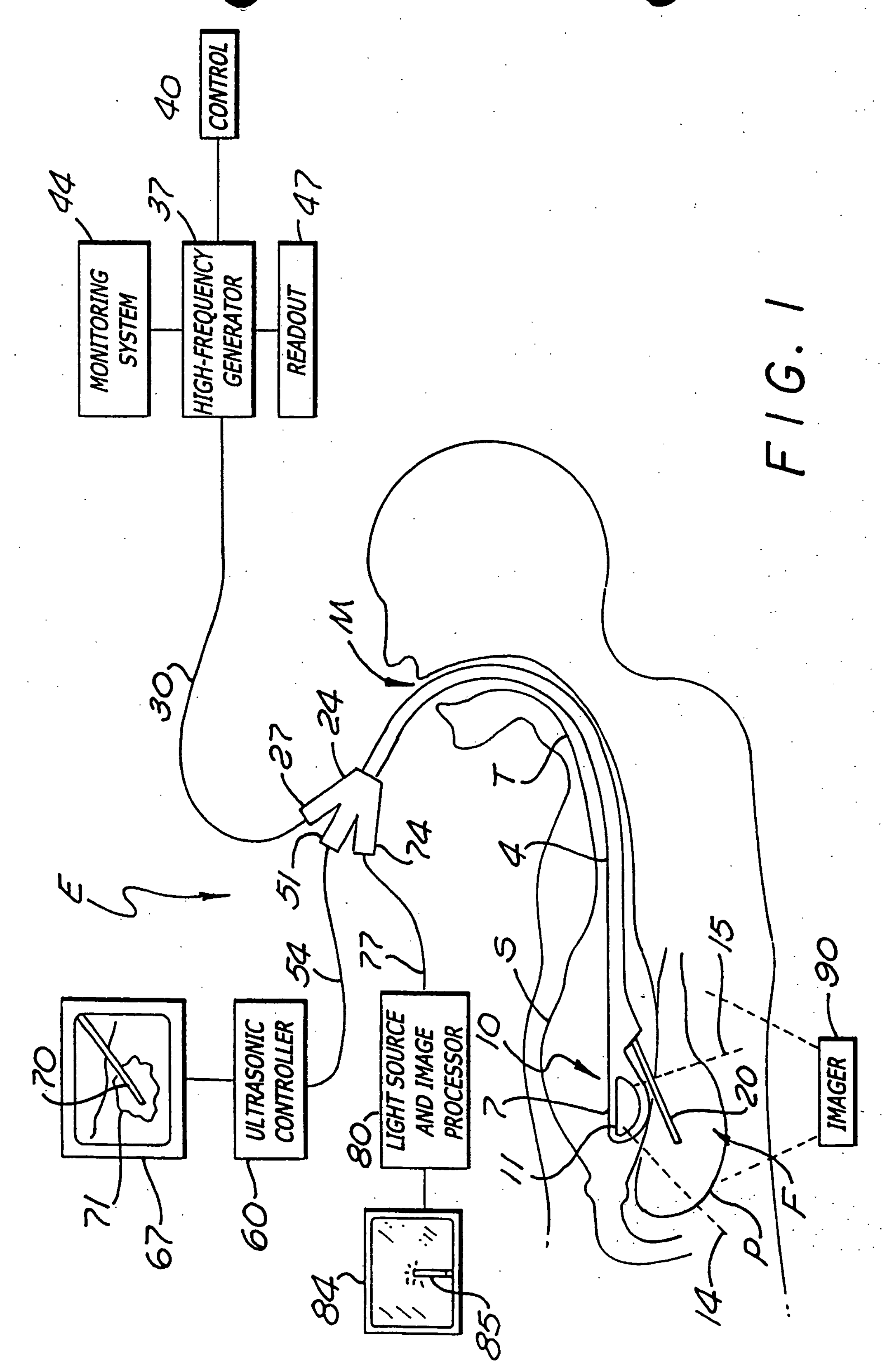
positioning a distal end of the endoscope at a point in the lumen near the target volume;

viewing a portion of the body with an imaging system located at the distal end of the endoscope;

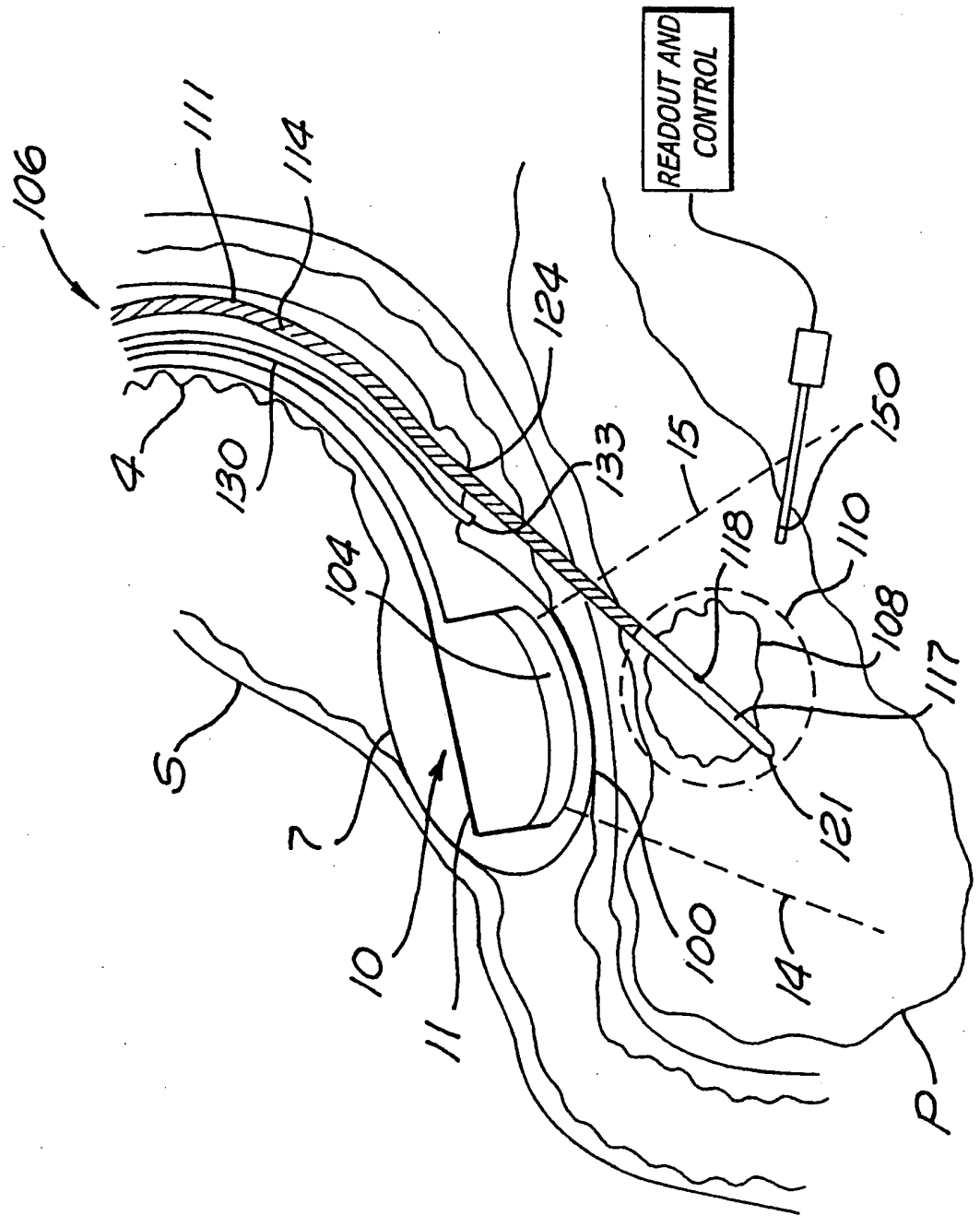
passing an ablator through the endoscope to the distal end of the endoscope;

penetrating a wall of the lumen with the ablator to reach the target volume; and

applying energy to the ablator to ablate the target volume.


CONTROL
40
MONITORING SYSTEM
44
HIGH-FREQUENCY GENERATOR
37
READOUT
47
30
M
27
24
T
4
51
74
E
54
77
5
10
15
90
IMAGER
ULTRASONIC CONTROLLER
LIGHT SOURCE AND IMAGE PROCESSOR
70
71
67
60
80
84
85
7
11
20
F
P
14

F I G. 1


READOUT AND CONTROL
106
111
114
124
4
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133
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150
104
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110
108
117
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7
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11
100
14
121
P

FIG. 2

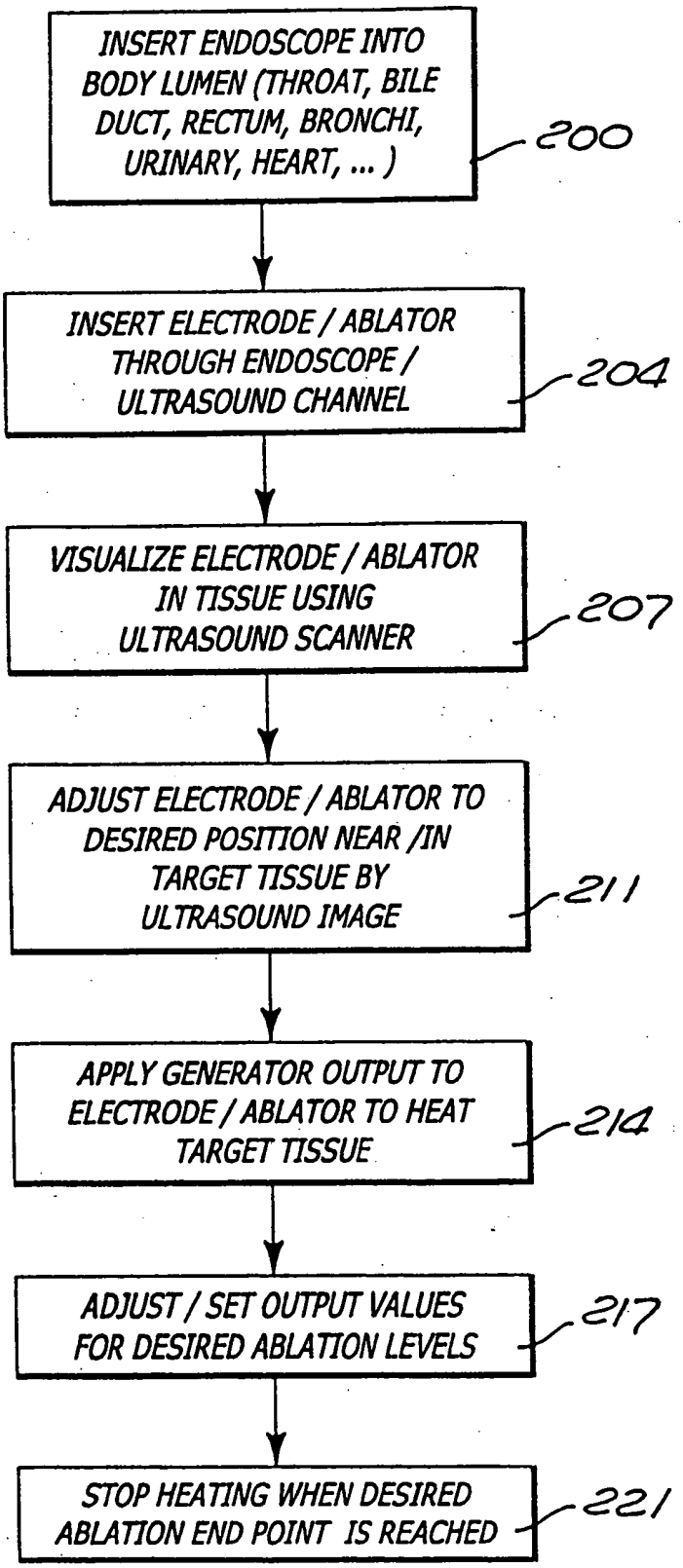
INSERT ENDOSCOPE INTO BODY LUMEN (THROAT, BILE DUCT, RECTUM, BRONCHI, URINARY, HEART, ...)
200
INSERT ELECTRODE / ABLATOR THROUGH ENDOSCOPE / ULTRASOUND CHANNEL
204
VISUALIZE ELECTRODE / ABLATOR IN TISSUE USING ULTRASOUND SCANNER
207
ADJUST ELECTRODE / ABLATOR TO DESIRED POSITION NEAR /IN TARGET TISSUE BY ULTRASOUND IMAGE
211
APPLY GENERATOR OUTPUT TO ELECTRODE / ABLATOR TO HEAT TARGET TISSUE
214
ADJUST / SET OUTPUT VALUES FOR DESIRED ABLATION LEVELS
217
STOP HEATING WHEN DESIRED ABLATION END POINT IS REACHED
221

FIG. 3

INTERNATIONAL SEARCH REPORT

Int tional Application No
P[redacted]S 99/09294

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 834 288 A (BLEWETT JEFFREY J ;STONE CORBETT W (US); MAURER CHRISTOPHER W (US)) 8 April 1998 (1998-04-08) abstract column 18, line 33-40; figure 35 ---	1-12
X	US 4 950 267 A (ISHIHARA KOICHIRO ET AL) 21 August 1990 (1990-08-21) column 2, line 39 - column 3, line 34; figures 1,2 ---	1-3,6-12
X	WO 80 02499 A (AMERICAN CYSTOSCOPE MAKERS INC) 27 November 1980 (1980-11-27)	1,2
A	page 7, line 16 - page 8, line 18 page 10, line 5-10 ---	9
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 August 1999	25/08/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hansen, S

INTERNATIONAL SEARCH REPORT

Inte tional Application No
PCT/US 99/09294

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 5 398 691 A (BASHEIN GERARD ET AL) 21 March 1995 (1995-03-21) column 4, line 48 - column 5, line 3 abstract; figure 1	1,5,6,9
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A	EP 0 382 974 A (BARD INC C R) 22 August 1990 (1990-08-22) abstract; figure 5	1,9

INTERNATIONAL SEARCH REPORT

ernational application No.
PCT/[redacted]99/ 09294

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13-19
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte ional Application No
PCT/US 99/09294

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Intr tional Application No
PC /US 99/09294

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